EXHIBIT G

DEPARTMENT OF HEALTH AND HUMAN SERVICES
UNITED STATES FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Joint Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) and the Psychopharmacologic Drugs Advisory Committee (PDAC)

Thursday, July 10, 2008

8:00 a.m.

Sheraton College Park Hotel
4095 Powder Mill Road
Beltsville, Maryland

PAPER MILL REPORTING
(301) 495-5831

C O N T E N T S

C O N T E N T S

P A R T I C I P A N T S

Larry B. Goldstein, M.D.,
Chair

Yvette Waples, Pharm.D.
Designated Federal Official

PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Britt Anderson, M.D., Ph.D.
Lily K.F. Jung, M.D., M.M.M. (Consumer Representative)
Ying Lu, Ph.D.
Matthew Rizzo, M.D.
Stacy Ann Rudnicki, M.D.

PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE MEMBERS (Non-Voting)

Roy E. Twyman, M.D.

PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Jorge Armenteros, M.D.
Rochelle Caplan, M.D.
Gail Griffith, M.L.S
Susan L. Schultz, M.D.
Robert F. Woolson, Ph.D.

PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Non-Voting)

William Z. Potter, M.D., Ph.D.

TEMPORARY VOTING MEMBERS

Ruth S. Day, Ph.D.
Sid Gilman, M.D, FRCP
Wayne Goodman, M.D.
Andrew Leon, Ph.D.
Richard Malone, M.D.
Daniel S. Pine, M.D.
Delbert G. Robinson, M.D.
Andrew Winokur, M.D., Ph.D.

P A R T I C I P A N T S (CONTINUED)

DRUG SAFETY AND RISK MANAGEMENT VOTING MEMBERS

Sean Hennessy, Ph.D.

PEDIATRIC ADVISORY COMMITTEE VOTING MEMBERS

Melissa Hudson, M.D.

FDA CENTER FOR DRUG EVALUATION AND RESEARCH PARTICIPANTS (Non-Voting)

Robert Temple, M.D.
Russell Katz, M.D.
Tom Laughren, M.D.
Alice Hughes, M.D.
Evelyn Mentari, M.D., M.S.
Mark Levenson, Ph.D.

a very serious adverse event. There is a difference that I calculated from the data presented is 5.8 per 10,000 treated patients. To me, it would help to put it in perspective to know whether other categories of death differed; in other words, was there an attempt to look at all-cause death between the two groups in the meta-analysis.

In some sense, if the only difference was suicide, that would probably by washed out by other causes of death. On the other hand, if the drugs cause beneficial effects that reduce the risk of death through other mechanisms, that would be important to know, and I would like to hear data on that if we have it.

DR. LEVENSON: We did not collect any data on all-cause death, so we do not have that data.

DR. GOLDSTEIN: We are just a couple of minutes after the top of the hour. We allowed about a five-minute wiggle room so we can take a couple more questions before we move on.

Next is Dr. Twyman.

DR. TWYMAN: I have a question around the data that went into the generalization that this is a class effect. I think someone else pointed out that there are a

lot of other compounds used in the United States that actually are not in this list per se. The data are obviously from more recently studied compounds and development programs.

My question is what potentially is the impact of the missing data--that is, the data from compounds in common use in the United States that are really not in this data set--and has there been an attempt to look at weaker data sets, say, the postmarketing vigilance database, to see whether or not there are some trending signals there because, obviously, we can't get at recent study data for these other compounds.

DR. KATZ: We have looked in at least one case of one drug at postmarketing for other purposes, and didn't convince ourselves that there was a signal. But I think we have long ago decided that postmarketing data are not the right data to look at, or we don't believe that for these sorts of things where there is a high background rate of suicidality so defined in these populations, I think we have concluded that postmarketing data is uninterpretable, and that is why we went to placebo-controlled trials.

It is impossible to know what the impact of other

non-studied drugs would be on this. Again, obviously, our proposal would say, well, we have studied 11, 9 which actually had enough patients to say something, about 8 of which all went in the same direction.

That is suggestive to us of a so-called effect. I realize we have to discuss that more. So, we don't know what would happen with other drugs not studied, but we do think that we do have pretty much all the relevant control trials done with these drugs in this analysis.

DR. GOLDSTEIN: Dr. Rizzo.

DR. RIZZO: Did anyone do a forensic analysis to try to determine if the four people who committed suicide actually did it because of anticonvulsants or not?

DR. KATZ: I don't think we did a forensic analysis. I am not personally sure what that is. I think it is very difficult to tell from the individual case reports whether or not--narratives of those four cases--whether or not the suicide was related to the treatment. I think that is why we are analyzing controlled trials.

DR. RIZZO: What I mean is call up the authors and ask them about the suicide and try and determine what happened, and, if necessary, get medical records. That is

what I mean by forensic analysis.

DR. KATZ: I don't believe we did that. I think again the companies gave us presumably all the relevant data that they had. Whether they made efforts in those particular cases to follow up, I hope they did, but I certainly couldn't testify that they did that in those cases. Is that a fair statement?

Again, I think looking at the individual narratives to try and figure out causality is more or less problematic. Again, that is why we are looking at the controlled trial data.

DR. RIZZO: It's what the FDA does, it is what NASA does, it is what the FAR system does. It is a very common process.

DR. KATZ: Again, in any individual case, depending on what the event is, it might be fairly easy to do from a narrative. In some cases, it is undoubtedly more ambiguous. But again we haven't done that in this case.

DR. TEMPLE: But you can look at it and reach a conclusion. But I don't know if you remember the antidepressant situation beginning in 1991. There were these very interesting horrible cases of people becoming